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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/699,987 | 11/03/2003 | Wing-Kee Philip Cho | 025444.1059-US02 | 5359 |

26853 7590 04/05/2007

COVINGTON & BURLING, LLP
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WASHINGTON, DC 20004-2401

| EXAMINER | |
|---|---|
| SHEIKH, HUMERA N | |
| **ART UNIT** | **PAPER NUMBER** |
| 1615 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|---|---|---|
| 31 DAYS | 04/05/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/699,987 | CHO, WING-KEE PHILIP | |
| | Examiner | Art Unit | |
| | Humera N. Sheikh | 1615 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *28 April 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *42-120* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *42-120* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### Status of the Application

Claims 42-120 are pending in this action. Claims 42-120 are subject to an Election/Restriction requirement.

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 42-71, drawn to a solid composition comprising an immediate release layer of desloratadine and a sustained release layer of pseudoephedrine, classified in class 424, subclass 472.

II. Claims 72-120, drawn to a solid composition comprising desloratadine, classified in class 424, subclass 465.

The inventions are distinct, each from the other because of the following reasons:

The invention of Group I (claims 42-71) is distinct from the invention of Group II (claims 72-120). Group I is drawn to a solid composition comprising (i) an immediate release layer of desloratadine and two pharmaceutically acceptable antioxidants; and (ii) a sustained release layer of pseudoephedrine and (iii) a sustained release agent, wherein the total amount of desloratadine degradation products in the solid composition is less than or equal to about 2% by weight. The invention of Group II is drawn to a solid composition comprising desloratadine and at least one pharmaceutically acceptable antioxidant. The inventions are distinct because they are comprised

of different components and are structurally different, as well. The invention of Group I is a *multi*-layered, *sustained release* formulation that requires *two* active ingredients, desloratadine & pseudoephedrine in combination with two antioxidants, and a sustained release agent, whereas, in contrast, the invention of Group II is a *single*-layered, *non*-sustained or non-controlled release formulation that requires only *one* active agent – desloratadine and does not require pseudoephedrine, as does the invention of Group I claims. The invention of Group I requires *two* pharmaceutically acceptable antioxidants, whereas the invention of Group II requires *at least one* antioxidant. The invention of Group II is also devoid of any sustained release agent, whereas Group I requires a sustained release agent. The different inventions would thus have different issues with regarding to patentability, enablement and written description. The different inventions would also require different searches in both patent- and non-patent databases and there is no expectation that the searches would be coextensive in scope. This creates an undue burden on the Examiner. Thus, the restriction/election requirement is deemed proper.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

***Note***: If Applicant chooses to elect **Group I** (claims 42-71), then the following further election of species is required:

This application contains claims directed to the following patentably distinct species:

**Method of treatment**:

(a) Method of treating allergic or inflammatory conditions of upper/lower airway passages;

(b) Method of treating the signs and symptoms of nasal congestion;

(c) Method of treating the signs and symptoms of urticaria;

(d) Method of treating nasal and non-nasal symptoms of perennial or seasonal allergic rhinitis.

The species are independent or distinct because each of groups (a-d) are drawn towards different methods of treatment, which may require different mechanisms of treatment and/or different drugs used to provide for the treatment.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

* * * * *

***Note***: If Applicant chooses to elect **Group II** (claims 72-120), then the following further election of species is required:

This application contains claims directed to the following patentably distinct species:

**Method of treatment**:

(a) Method of treating allergic or inflammatory conditions of upper/lower airway passages;

(b) Method of treating the signs and symptoms of urticaria;

(c) Method of treating nasal and non-nasal symptoms of perennial or seasonal allergic rhinitis.

The species are independent or distinct because each of groups (a-c) are drawn towards different methods of treatment, which may require different mechanisms of treatment and/or different drugs used to provide for the treatment.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

A telephone call was made to Paul J. Berman on 02/28/07 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

HUMERA N SHEIKH
PRIMARY EXAMINER

Art Unit 1615
March 22, 2007

*Hns*